PATENT

1742

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#17 1/2

In re Application of: J. M. Steinke, A.P. Shepherd	§	Examiner: K. Hantis
Serial No.: 07/953,680	§	Group Art Unit: 2505
Filed: September 29, 1992	§	
For: METHOD AND APPARATUS FOR DIRECT SPECTROPHOTOMETRIC MEASUREMENTS IN UNALTERED WHOLE BLOOD	§	Atty. Dkt.: UTSK:142/BAH

CERTIFICATE OF MAILING
37 C.F.R. § 1.8

I hereby certify that this correspondence is being deposited with the U.S. Postal Service as First Class Mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231, on the date below:

October 10, 1995 — David D. Bahler

Date — **David D. Bahler**

SUPPLEMENTAL DECLARATION OF A.P. SHEPHERD
UNDER 37 C.F.R. § 1.132

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

I, A. P. SHEPHERD, do hereby declare and state:

1. I am a co-inventor of the above-identified patent application, and remain the President and Chief Executive Officer of A-VOX Systems, Inc. I signed a Declaration Under 37 C.F.R § 1.132 on December 12, 1994, that was filed in the above-identified application on December 15, 1994. I have reviewed the

statements in my previous declaration, and believe them to be accurate today except as updated by statements herein.

2. I understand that the Examiner has stated on page 28 of the Office Action mailed April 26, 1995 that my prior declaration was given "little evidentiary value," in part because in paragraph 4 of that declaration, I stated that I believed that the AVOXimeter 1000 incorporated the subject matter of at least claim 1 of the present application. That statement meant only that I had not formed a belief as to what other claims of the present application were embodied in the AVOXimeter 1000. In fact I believe that claim 1 of the present application covers the core functions of the AVOXimeter 1000, and that, other than displaying the calculated concentrations, the AVOXimeter 1000 performs no other functions of consequence. In addition, since Examiner Hantis was present on January 19, 1994 at a demonstration of the AVOXimeter 1000, and since a brochure completely describing the functions of the AVOXimeter 1000 was attached to my prior declaration, it seems unreasonable for the Examiner to imply that the product had unclaimed functions that would somehow contribute to the commercial success of the product.

3. Without the aid of distributors, and using only direct-mail advertising, A-VOX Systems, Inc. sold approximately 34 AVOXimeter 1000's to hospitals in the United States in 1993. This resulted

in cash receivables totalling $261,513 for the oximeter and disposable optical cuvettes used with the oximeter.

4. In 1994, A-VOX Systems, Inc. sold approximately 94 AVOXimeter 1000's, resulting in accounts receivable of $692,665, for the oximeter and disposable cuvettes. This represents a 250% increase over the cash receivables for 1993.

5. During the first 6 months of 1995, A-VOX Systems,Inc. has sold approximately 58 AVOXimeter 1000's, resulting in accounts receivable of $450,000 for the oximeter and disposable cuvettes. This represents over 64% of the receivables for the entirety of 1994.

6. In addition, A-VOX Systems, Inc. has licensed the technology described in the above-identified patent application to Instrumentation Laboratory Company. Instrumentation Laboratory Company is a major manufacturer and marketer of blood gas analyzers throughout the world, and is the assignee of Brown *et al.*, U.S. Patent No. 4,134,678, of record in the above patent application. That license grants to Instrumentation Laboratory Company the exclusive right to incorporate A-VOX Systems patent and know how rights in non-portable, bench-top products used to measure one or more of the following: bilirubin concentration, total hemoglobin concentration, relative oxyhemoglobin concentration, relative deoxyhemoglobin concentration, relative

carboxyhemoglobin concentration, relative methemoglobin concentration, or relative sulfhemoglobin concentration. The license expressly defines patent and know how rights to include the information and discoveries described in U.S Patent Application Serial No. 07\953,680.

7. That license specifies a license initiation fee of $50,000, and a minimum royalty over the life of the agreement of over $1,000,000. If sales of the licensed product reach projected levels, the total royalty over the life of the agreement will exceed $11,000,000.

8. In addition to the AVOXimeter 1000 that is now in widespread use, A-VOX Systems has developed other products that exploit the present invention. The 1000 measures the relative concentration of oxyhemoglobin and the total hemoglobin concentration from which it computes the oxygen concentration. The model 2000 makes the same measurements, but also measures the relative concentration of methemoglobin. Finally, the model 4000, which is not on the market yet because it is awaiting clearance from the FDA, has all of the capabilities of the conventional co-oximeter. The AVOXimeter 4000 embodies at least claim 1 presently pending in the above-identified patent application. In the table and photograph attached as Exhibit 1 to this Declaration, the AVOXimeter 4000 is compared and contrasted with the Corning 2500, a typical co-oximeter.

9. An important trend in hospital practice and the medical marketplace today is "near-patient testing" or "point-of-care measurements." Small portable instruments that can be used by doctors and nurses rather than professional laboratorians are creating a revolution in medical practice because such instruments give fast on-the-spot results that improve patient care and therapy. I believe that the present invention can be developed into a series of such portable instruments because of the miniaturization illustrated in the table and photograph of Exhibit 1. In fact, A-VOX Systems has already developed a pocket-size, battery-powered hemoglobinometer, the Hb-Quick, which is awaiting clearance from the FDA. By contrast, I believe that the Corning 2500 and the other conventional hemolyzing co-oximeters represent a technological dead-end because the pumps, plumbing, ultrasonic hemolyzer, and the associated control circuitry that prior-art co-oximeters need to hemolyze and analyze the blood sample make such miniaturization impossible. Thus, in my opinion, only the oximeters and hemoglobinometers that employ the present invention will be able to exploit the market's trend toward "near-patient testing."

10. I hereby declare that all of the statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful, false statements and the like are punishable by fine and/or

imprisonment under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application, or any patent issuing therefrom.

14 August 1995
Date

A. P. Shepherd

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COMPARISON of AVOXimeter 4000 and Corning 2500

	Corning 2500	AVOXimeter 4000
Cuvette	permanent	disposable
Size	14 X 10.5 X 20.5 in.	10 X 8 X 3.75 in
Weight	52 lbs	4 lbs
Cost	$14,000	$6,950
Speed	90 sec/sample	10 sec/sample
Power	AC	batteries
Service Training Course	$5,000	not necessary

These two instruments make exactly the same measurements: total hemoglobin concentration and the relative concentrations of oxy-, deoxy-, carboxy-, and methemoglobin. The dramatic reductions in cost, size, weight, price, complexity, maintenance, and time per sample are all made possible because the present invention enables the AVOXimeter 4000 to make the measurements directly in whole blood without prior hemolysis of the sample.